CLAIMS

What is claimed is:

1. A composition comprising a substantially integral bARE class protein.

2. The composition according to claim 1, wherein the composition comprises a stabilising agent.

3. The composition according to claim 2, wherein the stabilising agent is a charged amino acid or an analogue thereof.

4. The composition according to claim 3, wherein the stabilising agent is Arginine or Arginine Phospate.

5. The composition according to claim 4, wherein the Arginine or Arginine phosphate is present in an amount of from about 100mM to about 400mM.

6. The composition according to claim 2, wherein the composition comprises an uncharged agent or an analogue thereof.

7. The composition according to claim 6, wherein the composition comprises a zwitterionic agent.

8. The composition according to claim 7, wherein the zwitterionic agent is a zwitterionic detergent.

9. The composition according to claim 8, wherein the zwitterionic detergent is 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS).

10. The composition according to claim 9, wherein the zwitterionic detergent is present in an amount of from about 0.05% to about 0.5% by weight per volume (w/v).

11. The composition according to claim 2, wherein the composition comprises a charged amino acid or analogue according to any one of claims 3-5 and an uncharged agent according to any one of claims 6-9.

12. The composition according to claim any one of claims 1-11, wherein the Integrity of the bARE class protein is determined with reference to an Integrity Ratio.

13. The composition according to any one of claims 1-12, wherein the bARE protein is an AB5 protein.

14. The composition according to claim 13, wherein the bARE protein is an LTK63 or LTK 72 protein.

15. A method of stabilising a bARE protein wherein the method comprises providing a bARE class protein and combining the bARE class protein with a stabilising agent.

16. The method according to claim 15, wherein the stabilising agent is a charged amino acid or an analogue thereof.

17. The method according to claim 16, wherein the stabilising agent is Arginine or Arginine Phosphate.

18. The method according to claim 17, wherein the Arginine or Arginine phosphate is present in an amount of from about 100mM to about 400mM.

19. The method according to claim 15, wherein the stabilising agent is an uncharged agent.

20. The method according to claim 19, wherein the uncharged agent is a zwitterionic agent.

21. The method according to claim 20, wherein the zwitterionic agent is a zwitterionic detergent.

22. The method according to claim 21, wherein the zwitterionic detergent is 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS).

23. The method according to claim 22, wherein the zwitterionic detergent is present in an amount of from about 0.05% to about 0.5% by weight per volume (w/v).

24. The method according to claim 15, wherein the stabilising agent comprises a charged amino acid according to any one of claims 16-18 and an uncharged agent according to any one of claims 19-23.

25. The method according to any one of claims 15-24, wherein the stabilising of the bARE class protein is determined with reference to an Integrity Ratio.

26. The method according to any one of claims 15-25, wherein the bARE protein is an AB5 protein.

27. The method according to claim 26, wherein the AB5 protein is an LTK63 or LTK 72 protein.

28. A method of analysing a bARE class protein under non-dissociating conditions which differentiate between integral and dissociated bARE class proteins.

29. The method according to claim 28, wherein the method comprises a separation step on a charged polymeric separation material.

30. The method according to claim 29, wherein the polymeric separation material is a hydrogel monomer.

31. The method according to claim 30, wherein the hydrogel monomer is a hydroxylated polymethacrylate (HEMA) monomer.

32. The method according to claim 31, wherein the HEMA has a particle size of about 6 microns.

33. The method according to claim 31 or 32, wherein the HEMA has a porosity of about 250A.

34. A method of analysing a bARE class protein wherein the method comprises:
(i) applying a bARE class protein to a charged polymeric separation material in an apparatus configured to resolve an integral bARE class protein from a dissociated bARE class protein;

(ii) treating the separation material comprising the applied bARE class protein with an ionic buffer; and

(iii) detecting one or more integral or dissociated bARE class proteins.

35. The method according to claim 34, wherein the separation material is as defined in any one of claims 30-33.

36. The method according to claim 34 or 35, wherein the ionic buffer is a physiologically acceptable buffer with a pH of from about 7.0 to about 8.0.

37. A method for identifying a bARE class protein stabilisation agent wherein the method comprises:

(i) combining a bARE class protein with a candidate stabilising agent to form a bARE protein sample;

(ii) applying the bARE protein sample to a charged polymeric separation material in an apparatus configured to resolve an integral bARE class protein from a dissociated bARE class protein;

(iii) treating the separation material comprising the applied bARE class protein with an ionic buffer;

(iv) detecting one or more integral or dissociated bARE class proteins; and

(v) determining whether the candidate stabilising agent is a bARE protein stabilising agent.

38. The method according to claim 37, wherein the method comprises calculating an Integrity Ratio for the bARE protein sample.

39. The method according to claim 38, wherein the method further comprises comparing the Integrity Ratio for the bARE protein sample with an Integrity Ratio for a control without a candidate stabilising agent.

40. A stabilising agent identified by the method of any one of claims 37-39.

41. The stabilising agent according to claim 40, which is a functional stabilising agent.

42. The stabilising agent according to claim 40, which is a physical stabilising agent.

43. An immunogenic composition comprising a composition according to any one of claims 1-14.

44. An immunogenic composition according to claim 43, wherein further comprising an adjuvant, wherein said adjuvant is not the bARE protein.

45. An immogenic composition according to claim 44, wherein the adjuvant is a mucosal adjuvant.

46. Use of a composition according to any one of claims 1-14 in the preparation of a medicament to prevent and/or treat an immune disorder.

47. A method of treating a mammal to prevent and/or treat an immune disorder comprising administering a composition according to any one of claims 43-45.

48. A method according to claim 47 wherein the mammal is a human.

49. Use of a charged agent to physically stabilise a bARE protein.

50. Use according to claim 49 wherein the charged agent is charged amino acid base.

51. Use according to claim 50 wherein the charged amino acid is a positively charged amino acid.

52. Use according to claim 51 wherein the positively charged amino acid is Arginine or Arginine Phospate or an analogue thereof.

53. Use of an uncharged agent or an analogue thereof to functionally stabilise a bARE protein.

54. Use according to claim 53, wherein the uncharged agent is zwitterionic agent.

55. Use according to claim 54 wherein the zwitterionic agent is a zwitterionic detergent.

56. Use according to claim 55 wherein the zwitterionic detergent is is 3-(3-Cholamidopropyl)-dimethylammonio-1-propanesulfonate (CHAPS).

57. Use of a combination of a charged agent and an uncharged agent or analogues thereof to stabilise a bARE protein.

58. Use according to claim 57 wherein the charged agent is defined in any one of claims 50-52 and the uncharged agent is defined in any one of claims 53-56.

59. Use according to any one of claims 49-58 wherein the bARE protein is an AB5 protein.

60. Use according to claim 60 wherein the AB5 protein is LTK63 or LTK72.